

Remarks

This Amendment is in response to the Office Action dated **March 21, 2008**.

Rejections

35 U.S.C. §102(b)

Claims 1, 2, 4-8, 10-33, and 35-52 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698). It is asserted in the Final Office Action, page 2, that “Hanson discloses in Figures 2, 7, and 8 a balloon comprising a torque having a first unexpanded state (Figure 2), an unexpanded state (Figure 7), and a second unexpanded state (Figure 8); the balloon being mounted on an inner shaft (22); and an outer shaft (66).”

Applicants traverse the rejection.

Independent claim 1 of the present application is directed to an expandable medical balloon having first unexpanded state, an expanded state and a second unexpanded state, the balloon is mounted on an inner shaft of a catheter assembly, the inner shaft having a torque in the first unexpanded state of said balloon, the balloon having a torque in the first unexpanded state and having a torque in the second unexpanded state.

Independent claim 22 is directed to a balloon catheter having an expandable member formed according to a method including the steps, among others, of mounting an expandable balloon member on an inner shaft, and applying a torque to the inner shaft such that a torque is applied to said balloon member, the torque being applied to the inner shaft so that the inner shaft has the torque in said first unexpanded state of the expandable member.

Independent claim 33 is also directed to a method of providing an expandable member of a balloon catheter with improved rewrap, the method including the steps of, among

others, mounting the balloon member on an inner shaft; and applying a torque to the inner shaft resulting in application of a torque to the balloon member, the torque being applied so that the inner shaft has the torque when the balloon member is in the first unexpanded state.

In order for a reference to anticipate, each and every element of the claimed invention must be disclosed by that single reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP 2131.

Applicants submit that Hanson fails to disclose that the inner shaft (22) has a torque as recited in Applicants' claims 1, 22 and 33. In fact, Hanson discloses the opposite:

In accordance with the invention, the provision of the thin support wire 50 rotatably disposed in the gas supply tube permits the support wire to be rotated or swiveled relative to the gas supply tube, thereby permitting the balloon to be easily and compactly twisted about the support wire. This results in the twisted balloon having a smaller cross-sectional area which approaches that of tip 32 and gas supply tube 22. Thus, the overall cross-sectional area of catheter 20 may be reduced for insertion into smaller incisions. Additionally, the torque applied to twist the balloon during wrapping thereof is not imparted to the gas supply tube thereby preventing stress to and damage of the gas supply tube.

Hanson, US 4346698, col. 5, lines 7-20 (emphasis added)

Therefore, the reference fails to disclose each and every element of claim 1 as required by 35 U.S.C. §102(b). Claims 2, 4-8 and 10-21 depend from claim 1 and are not anticipated by Hanson for at least the reasons that claim 1 is not anticipated by Hanson.

Claims 23-32 depend from claim 22, and claims 35-51 depend from claim 33 and are not anticipated by Hanson for at least the reasons that claims 22 and 33 are not anticipated.

Independent claim 52 is directed to an expandable medical balloon, the expandable medical balloon comprising a proximal waist portion, a proximal cone portion, a body, a distal cone portion and a distal waist portion, the balloon secured to an inner catheter shaft at the distal waist portion and secured to an outer shaft at the proximal waist portion, the balloon further

having a first unexpanded state and a second unexpanded state, the balloon having a torque in the first unexpanded state and in the second unexpanded state.

Claim 52 has been amended to correct a typographical error. The balloon is secured to the outer shaft at the proximal waist portion. See page 4, paragraph at lines 22-30. No new matter has been added.

The second unexpanded state recited in claim 52, refers to the unexpanded state when the balloon is deflated it is again torqued, as if it has a “memory” of the original torque, and the torque in the inner is released. This results in better rewrap of the balloon member after an initial inflation. The memory remains even if the balloon is inflated and deflated more than once. See page 2, lines 24-34 and page 3, lines 1-2.

Applicants submit that Hanson also fails to disclose that the balloon retorques after deflation. In fact, Applicants submit that Hanson discloses the opposite. This is apparent from the statements found at col. 5, lines 48-49: “The sheath also prevents the balloon from unwinding....In addition to locking the balloon in its twisted configuration, the sheath is smooth-walled and, as mentioned, is made of low friction material to facilitate insertion of the catheter.” This disclosure would be understood as indicating that the balloon does not have a memory of the twist, but rather, the twist is no longer present once the sheath is removed.

In contrast, Applicants’ balloon will retorque when deflated. See page 8, lines 24-31.

Therefore, claim 52 is also not anticipated by Hanson.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4-8, 10-33, and 35-52 under 35 U.S.C. §102(b) as being anticipated by Hanson (US 4,346,698).

35 U.S.C. §103(a)

Claim 9 has been rejected under 35 U.S.C. 103(a) as being obvious over Hanson as modified by Kletschlka (US 6,443,926). It is asserted that “Hanson et al disclose the claimed invention except for the device comprising a stent. Kletschlka disclose in column 8, lines 1-4 that it is known to use a stent in this type of medical device.” Final Office Action, pp. 2-3.

Applicants traverse the rejection.

Claim 9 depends from claim 1.

As discussed above, Hanson does not disclose that the inner catheter shaft has a torque.

Combining a stent as disclosed by Kletschlka fails to render claim 1 obvious because the combination fails to disclose or suggest the element of an inner catheter shaft with a torque as recited in claim 1.

Claim 9 is not obvious over Hanson in view of Kletschlka for at least the reasons that claim 1 is not obvious.

Applicants respectfully request withdrawal of the rejection of claim 9 under 35 U.S.C. §103(a) as being obvious over Hanson as modified by Kletschlka (US 6,443,926).

CONCLUSION

Claims 1, 2, 4-33 and 35-52 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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Date: May 15, 2008

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